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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,326	08/21/2003	Amel Amblard	8707-2161	7566

7590 03/07/2006

Orrick, Herrington & Sutcliffe LLP
666 Fifth Avenue
New York, NY 10103

EXAMINER

ALEXANDER, JOHN D

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,326	AMBLARD, AMEL	
	Examiner	Art Unit	
	John D. Alexander	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 21-25 is/are rejected.
- 7) ☒ Claim(s) 19, 20, 26 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/21/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed August 21, 2003, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the foreign document EP 0 550 342 has not been considered because no English translation was provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether Applicant is attempting to claim detecting conditions indicative of suspected loss of atrial detection or detecting conditions indicative of suspected loss of atrial detection *and suspected loss of atrial capture*. From Applicant's specification, it seems that the condition recited in lines 10-12 of Claim 1 (i.e. an occurrence of an atrial detection consecutive to an atrial stimulation over a predetermined number of successive cardiac cycles) is used only for detection of suspected loss of atrial *capture*. Yet, this condition is claimed as one indicative of suspected loss of atrial *detection*. When examining the claims as to the merits,

examiner has assumed that Applicant has intended to only claim detecting conditions indicative of suspected loss of atrial detection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 5, 8-15, 17, 18, 21, 22, 24, and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11, and 12 of copending Application No. 10/645,329. Although the conflicting claims are not identical, they are not patentably distinct from each other, because the ‘329 application includes

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all of the limitations recited in Applicant's subject Claims, but the '329 claims encompass a narrower scope by being more specific and including more elements. Thus these claims of '329 are in effect a "species" of the "generic" invention of Applicant's subject Claims 1, 2, 4, 5, 8-15, 17, 18, 21, 22, 24, and 25. It has been held that the generic invention is "anticipated" by the "species." *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since Applicant's subject Claims 1, 2, 4, 5, 8-15, 17, 18, 21, 22, 24, and 25 are anticipated by '329 claims 1, 11, and 12, they are not patentably distinct therefrom.

Claims 3, 16, and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 11 of copending Application No. 10/645,329 in view of Zhang et al. (Patent No. 6418343). Application '329 does not explicitly claim that the increase of detection sensitivity is stopped in response to a detected return to normal atrial detection. Zhang et al. disclose a system and method for managing the atrial sensitivity of implantable cardiac pacemakers or defibrillators and include a teaching that, as the sensitivity is decreased, there exists a danger of false detection of depolarization events from sources such as noise or far-field T-waves (Col. 1, lines 30-52; Col. 2, lines 8-13). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Zhang et al. to modify Claims 1 and 11 of Application '329 to include stopping the increase of detection sensitivity in response to a detected return to normal atrial detection. The motivation would have been to prevent the danger of false detection of depolarization events from sources such as noise or far-field T-waves.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Sun et al. (Patent No. 6129745).

- Regarding **Claim 1**, Sun et al. disclose means for determining a long interval between atrial events, which examiner considers to meet Applicant's "coupling interval" limitation, (Col. 4, lines 65-67; Col. 5, lines 48-67) and means for suspecting loss of atrial detection upon detecting a condition of ventricular extrasystole in the presence of the greater coupling interval (Col. 6, lines 25-35).
- Regarding **Claim 2**, Sun et al. further disclose means for increasing the atrial detection sensitivity in response to the detected condition (Col. 3, lines 42-48; Col. 11, lines 11-13).
- Regarding **Claim 3**, Sun et al. further disclose that, when detection sensitivity is increased, a procedure is implemented to provide a check against oversensing (Col. 3, lines 42-50). Here, examiner considers that this procedure would inherently include stopping the increase of sensitivity once successful atrial detection is achieved.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Hill et al. (Patent No. 6195584). Hill et al. disclose means for suspecting loss of atrial detection caused by atrial lead dislodgment, wherein the means include detecting a reduction below a given limit of the

delays between atrial stimulations and ventricular detections (Col. 3, lines 41-48; Col. 8, lines 60-62; Col. 12, lines 47-67; Col. 13, lines 1-5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. in view of Hill et al. Sun et al. disclose the means related above for treating loss of atrial detection caused by improper atrial sensitivity settings, and also teach that loss of atrial detection can be caused by atrial lead dislodgment (Col. 1, lines 38-59). However, Sun et al. do not explicitly disclose a further means of suspecting loss of atrial detection that includes detecting a reduction below a given limit of the delays between atrial stimulations and ventricular detections. As related above in rejection of Claim 14, Hill et al. teach such means. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Hill et al. to modify Sun et al.'s detection means for loss of atrial detection to further include detecting a reduction below a given limit of the delays between atrial stimulations and ventricular detections. The motivation would have come from Sun et al.'s discussion of loss of

detection caused by atrial lead dislodgement and from Hill et al.'s teachings for a means to detect this type of undersensing.

Allowable Subject Matter

Claims 4, 5, and 9-13 would be allowable upon a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) *and* if rewritten to overcome the rejections under 35 U.S.C. 112, 2nd paragraph, *and* to include all of the limitations of the base claim and any intervening claims. **Claims 6 and 7** would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. **Claims 15-18** would be allowable upon a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) and if rewritten to include all of the limitations of the base claim and any intervening claims. **Claims 19 and 20** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. **Claims 21-25** would be allowable upon a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d). **Claims 26 and 27** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

- Regarding **Claims 4 and 9**, as related above, the prior art of record discloses implantable medical devices that include means for suspecting loss of atrial detection by detecting a condition of ventricular extrasystole (Sun et al.). The prior art also discloses devices such as these that further include means for increasing the atrial detection sensitivity in response to

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the detected condition. However, with the exception of Application '329, it seems that the art does not disclose or reasonably suggest such a device that includes the further functionality of stopping the increase of detection sensitivity in response to a detected return to atrial stimulation with a normal delay between atrial stimulation and ventricular detection.

- Regarding **Claims 5 and 10**, it further seems that, with the exception of Application '329, the art does not disclose or reasonably suggest the device of Claims 1 and 2 that also includes the functionality of restoring the atrial sensitivity to the initial setting in response to a detected return to atrial stimulation inducing a nonpathological delay between atrial stimulation and ventricular detection.
- Regarding **Claims 6 and 7**, it further seems that the prior art does not disclose or reasonably suggest the device of Claims 1 and 2 that also includes the functionality of periodically decreasing the atrial detection sensitivity in response to it being greater than the initial setting.
- Regarding **Claims 11-13**, it seems that, with the exception of Application '329, the art does not disclose or reasonably suggest the device of Claims 1 and 2 that also includes the functionality of detecting a passage from an atrial detection to an atrial stimulation with concomitant reduction, below a given limit, of a delay between an atrial event and a ventricular detection.
- Regarding **Claims 15-20**, as related above, Hill et al. disclose means for suspecting loss of atrial detection, wherein the means include detecting a reduction below a given limit of the delays between atrial stimulations and ventricular detections. However, because the prior art such as Hill et al. is concerned with loss of detection caused by lead dislodgment, it seems

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that there would be no motivation to include the further functionality of increasing the atrial detection sensitivity in response to the detected loss. Therefore, with the exception of Application '329, it seems that the art does not disclose or reasonably suggest the device of Applicants Claim 14 that also includes the functionality of increasing the atrial detection sensitivity in response to the detected loss.

- Regarding **Claims 21-27**, it seems that, with the exception of Application '329, the art does not disclose or reasonably suggest means for suspecting loss of atrial detection by detecting a passage from an atrial detection to an atrial stimulation with concomitant reduction, below a given limit, of a delay between an atrial event and a ventricular detection.

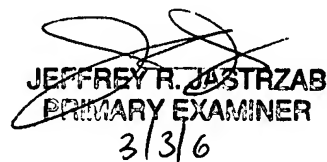
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Alexander whose telephone number is (571) 272-8756. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDA



JEFFREY R. JASTRZAB
PRIMARY EXAMINER
3/3/6